University of Virginia Medical Center
Clinical Practice Guideline

TITLE: Research in Patient Care Settings

This is a Guideline (recommended best practice)

OBJECTIVE:

To establish requirements for effective communication when human subject research (i.e., IRB Human Subjects Research and IRB Social Behavioral Sciences Research) occurs in inpatient, diagnostic/ interventional, and ambulatory settings.

PATIENT POPULATION:

☒Adult Acute Care
☒Adult Critical Care
☒Adult Ambulatory Care
☒Diagnostic/Procedural
☒Emergency Dept
☒Neonatal
☒Pediatric Ambulatory Care
☒Pediatric Inpatient Care
☒Perioperative
☒OTHER: _____

COMMUNICATION BEFORE A STUDY BEGINS

Before a study begins, the Principal Investigator (PI) or designee must:

i. Review the purpose and procedures of the proposed study, including how the study may impact patient care processes, with the Service Line/facility Leaders [which includes the administrator and medical director of the study-involved unit(s) and any pass through units where the patient would continue to be enrolled throughout the study (e.g., ICU, PACU, Radiology, Cath Lab, etc.)].

ii. Discuss with the Service Line/facility Leaders the nursing support required during the study (e.g., if nurses are required to collect data).

iii. Provide the Unit Based Leadership (UBL) (nurse manager and medical director) on the study-units and pass-through units/facilities with a brief overview of the purpose and procedures of the proposed study and collaboratively discuss the impact of the study on patient care and work flows on the unit/facilities involved.

iv. Provide contact information should study-related questions arise.

Use the Clinical Operations Directory as a resource for identifying affected area leadership:
https://www.medicalcenter.virginia.edu/intranet/pnso/ccsdirectory/

COMMUNICATION DURING THE STUDY

A. During the study period, the PI or designee must:

i. Maintain communication with the UBL regarding the study timeline, IRB-approved modifications to the study, and other related issues. Depending on the nature of the study, communications with pass-through unit communications may be broad in scope, while unit(s)/facility where study-specific procedures are performed would be expected to require more detail.

ii. Notify the UBL(s) when the study period in their unit/facility is completed, and close-out the unit/facility participation in the study; this shall include removal of study-related information from the unit/facility research binder/shared computer drive.

iii. Report and/or provide a summary of study results to the Service Line/facility Leadership, UBL and unit/facility staff.

B. During the study period, the UBL of the study unit/facility and any pass through unit must:
   i. Review the proposed study with the PI or designee.
   ii. Arrange in-services for the unit/facility staff by the PI or designee if appropriate.
   iii. Continually assess the ongoing impact and resource utilization of the study in the involved unit(s)/facilities and provide feedback to the PI or designee.

C. The Patient Care Team must:
   i. Recognize when their patients are subjects in a research study and seek additional information, if necessary, from the study team.
   ii. Use resources, including contacting the PI or designee, when questions regarding patient care related to the research protocol arise.
   iii. Contact the PI or designee when patients or families have any questions or concerns regarding the research protocol.
   iv. Notify the PI or designee when the protocol could not be followed / completed for any reason and for any reportable incident/untoward event that occurs related to the research.
   v. Notify the PI or designee, or a UVA IRB (e.g. IRB for Health Sciences Research, IRB for Social and Behavioral Research), if the patient lacks understanding of information about the research protocol, or other concerns relating to the research protocol.

D. The PNSO Nursing Research Lead can also serve as a liaison between research teams and patient care teams if questions or concerns arise (email PNSO@virginia.edu). For further information, please review PNSO Research Office Website.

ADDITIONAL INFORMATION:

Patients involved in selected human subject research studies will be flagged in the EMR.

DISCLAIMER:
Protocols contain a specific, established set of actions expected to be followed by clinicians. Guidelines provide evidence-based recommendations to assist practitioners in making decisions for patient care. However, guidelines and protocols are general and cannot take into account all of the circumstances of a particular patient. Judgment regarding the propriety of using a specific protocol or guideline with a particular patient remains with the patient's physician, nurse, or other health care professional, taking into account the individual circumstances presented by the patient. Care providers should document any deviations from protocol / guideline in the patient's electronic medical record, including the rationale for deviation.

Date	Version	Substantive changes made	Owner(s) Name, Credentials, Title	Committee Approval & Date*
	1.0	Initial version	Holly Hintz, Lisa Letzkus	Patient Care Cmte 12/6/18, 2/7/19

***Adults-** Patient Care Committee approval is required if the guideline will be used in multiple areas or if the local area does not have a practice committee to approve the guideline. If approval is required through other committees (such as MUSIC, P&T, infection control, etc.), please list those committees and dates of approval as well.

***Pediatrics-** Children's Hospital Clinical Practice approval is required if the guideline will be used in multiple areas or if the local area does not have a practice committee to approve the guideline. If approval is required through other committees (such as MUSIC, P&T, infection control, etc.), please list those committees and dates of approval as well.